

8EHQ-0195-13313

PUBLIC COPY

January 25, 1995

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Express Mail - Return Receipt Requested

Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460

8EHQ-45-13313
INIT
88950000102

COMPANY SANITIZED

Dear 8(e) Coordinator:

BENZOHETEROCYCLE

This letter is to inform you of the results of an approximate lethal dose study in mice. The test material was administered once by gavage to male mice at dose levels of 12 to 670 mg/kg. Death occurred in the mouse dosed at 670 mg/kg. Clinical signs, including incoordination, barrel-rolling, low posture, and low carriage, were observed in this mouse and are detailed in the enclosed report. The test material appears to have an approximate lethal dose of 670 mg/kg.

Under these experimental conditions, the clinical signs described above would appear to be reportable, based upon EPA guidance regarding the reportability of such data under TSCA Sect. 8(e) criteria.

A copy of the final report is enclosed.

Sincerely,

mm
0/1/95

RECEIVED
55 JAN 27 PM 2001

[]

CBI Substantiation

Support for [] claim of confidential business information for the information claimed as CBI is provided.

1. Confidential treatment should be afforded for ten years. Information should remain confidential until that time [].

2. No.

3. [] identity and the chemical identity [] are only disclosed to a second party [] under a nondisclosure (secrecy) agreement. [] has not otherwise disclosed the information claimed as CBI to other parties.

4. All documents relating to [] are stored in locked, limited-access facilities and designated as proprietary, trade secret or confidential. [] having access to the information are contractually prohibited from disclosing [] proprietary/confidential information outside the [].

5. No.

6. Yes. [] Disclosure of the CBI information would permit a competitor to specifically know and understand [] efforts and to forego the necessary time and expense to identify/ develop this compound, thus capitalizing on []. [] believes that a competitor's knowledge of the chemical identity [] interest in this compound would give a competitor several years advantage [] and would allow it to forego much of the R&D costs that it would otherwise have to bear. [].

7. a. No.

b. Yes. The chemical identity [] would, potentially, disclose proprietary mixture [].

c. Yes. Disclosure of [] would reveal the identity and source of the [].

Oral Approximate Lethal Dose (ALD) Study with

The oral approximate lethal dose study with
was conducted in male mice. The study was conducted
according to Standard Operating Procedure No. SE113-P-001,

The test substance was suspended in Mazola® corn oil/acetone
(85:15) and administered by oral gavage to one male mouse each at dosages
of 12, 17, 26, 40, 60, 90, 130, 200, 300, 500, or 670 mg/kg. Experimental
details of the study are archived in Quality Assurance and in laboratory
notebook

Death occurred in the mouse dosed at 670 mg/kg. This mouse exhibited
incoordination, ruffled fur, and yellow-stained perineum and had weight
loss of approximately 10% of initial body weight by 2 days after dosing.
No other clinical signs of toxicity were observed in this mouse until 11
days after dosing. Incoordination, barrel-rolling, low posture, and low
carriage were present. Weight loss of approximately 27% of the previously
determined body weight (8 days after dosing) was also observed. The mouse
was found dead 12 days after dosing.

Weight loss of up to approximately 9% of initial body weight was
observed up to 2 days after dosing in mice dosed at 26, 60, 90, 130, 200,
or 500 mg/kg.

Under the conditions of this test, an approximate lethal dose for
was 670 mg/kg. This substance is considered to be slightly toxic
(ALD 500-5000 mg/kg) when administered as a single oral dose to male mice.

Issue date: 1/5/95

Triage of 8(e) Submissions

Date sent to triage: APR 19 1985

NON-CAP

CAP

Submission number: 13313A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 pages 3 - pages 1, 3

Notes:

Contractor reviewer :

PAR

Date:

3/21/85

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHQ 0195-13313 ⁽³⁾ SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: Confidential

INFORMATION REQUESTED: FLWP DATE:

0501 NO INFO REQUESTED

0502 INFO REQUESTED (TECH)

0503 INFO REQUESTED (VOL ACTIONS)

0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:

0639 REFER TO CHEMICAL SCREENING

0678 CAP NOTICE

VOLUNTARY ACTIONS:

0400 NO ACTION REPORTED

0402 STUDIES PLANNED/IN PROGRESS

0403 NOTIFICATION OF WORKING CONDITIONS

0404 LABEL/MSDS CHANGES

0405 PROCESS/ANALYTICAL CHANGES

0406 APP/USE DISCONTINUED

0407 PRODUCTION DISCONTINUED

0408 CONFIDENTIAL

SUB. DATE: 01/25/95 OTS DATE: 01/27/95 CSRAD DATE: 02/01/95

CHEMICAL NAME:

Benzoheterocycle

CAS#

Confidential

INFORMATION TYPE:

P F C

INFORMATION TYPE:

P F C

INFORMATION TYPE:

P F C

0201	ONCO (HUMAN)	0216	EPICLIN	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	0217	HUMAN EXPOS (PROD CONTAM)	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	0218	HUMAN EXPOS (ACCIDENTAL)	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	0219	HUMAN EXPOS (MONITORING)	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	0220	ECO/AQUA TOX	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	0221	ENV. OCCURRENCE/FATE	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	0222	EMER INCI OF ENV CONTAM	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	0223	RESPONSE REQUEST DELAY	0248	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	0224	PROD/COMP/CHEM ID	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	0225	REPORTING RATIONALE	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	0226	CONFIDENTIAL			
0212	ACUTE TOX. (ANIMAL)	0227	ALLERG (HUMAN)			
0213	SUB ACUTE TOX (ANIMAL)	0228	ALLERG (ANIMAL)			
0214	SUB CHRONIC TOX (ANIMAL)	0239	METAB/PHARMACO (ANIMAL)			
0215	CHRONIC TOX (ANIMAL)	0240	METAB/PHARMACO (HUMAN)			

TRIAGE DATA: NON-CBI INVENTORY

YES

NO

IN INHIBIT

UNCLASSIFIED

Non-CBI

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER

SPECIES

MS

TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

USE:

PRODUCTION:

8(E) -13313A

M

ACUTE ORAL TOXICITY IN MALE MICE IS OF MEDIUM CONCERN. DOSAGES (GAVAGE), WITH ONE ANIMAL/DOSE, WERE 12 MG/KG TO 670 MG/KG. MORTALITY OCCURRED AT 670 MG/KG. TOXICITY SIGNS INCLUDED LOSS OF COORDINATION, LOW POSTURE, AND LOW CARRIAGE.